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MEDICALODGES PAOLA	501 ASSEMBLY LANE PAOLA, KS 66071

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F 000	INITIAL COMMENTS The following citations represent the findings of a Health Resurvey.	F 000		
F 253 SS=E	483.15(h)(2) HOUSEKEEPING & MAINTENANCE SERVICES The facility must provide housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior. This REQUIREMENT is not met as evidenced by: The facility reported a census of 83 residents. Based on observation and interview, the facility failed to provide housekeeping and maintenance services to maintain a sanitary and comfortable interior for the residents of the facility. Findings included: - On 8/1/12 from 2:30 pm to 4:00 pm, during an environmental tour of the facility, completed with maintenance staff B, and housekeeping staff C, acknowledged the following areas of concerns: Intermittent dirt and grime build-up at the edge of the wall and floor throughout the facility, especially at each of the door ways. On 8/1/12 at 12:09 pm, housekeeping staff D reported, "We got new mops that push the dirt to the sides." The "Country Store" contained black dirt and dust on the floor, approximately 6 to 12 inches outward, around the base of the walls. The half door, within this room, contained a layer of black dirt and dust on the trim boards. Housekeeping staff C reported, "We don't have a key for this	F 253		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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room. We [housekeeping staff] don't clean this room."

On the South Hallway:

1.) One of the 2 common resident shower/bath rooms, contained a 3 by 9 inch area of missing flooring, and exposed 2 different previous flooring materials.

2.) One of the 2 common resident shower/bath rooms, contained a black substance in the corners of the shower, along the base of the wall, upward approximately 7 inches high on the wall on 3 corners, and along a 2 foot area on the shower side of the raised shower threshold. Housekeeping staff C reported nursing should clean the shower area with each resident's shower.

3.) One of the 14 resident bathrooms, contained a 2 by 4 foot area of yellow staining on the tile wall beside the toilets.

4.) One of the 14 resident bathrooms, contained a 1 by 2 foot area of a brownish gray discoloration on the flooring beside the toilet.

5.) Five areas within the corridor lacked and/or contained loose wall paper including; 2 areas around blank electrical box covers, a 4 by 6 inch area above the doorway to the television room, loose wall paper 3 inches by 18 inches behind a fire door, and a border paper 2 foot in length at an exit door.

On the North Hallway:

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1.) Two of the 2 common resident shower/bath rooms contained flooring with a 1/2 to 1 inch gap between the edge of the flooring and the wall, which exposed older flooring material; thus making this a difficult surface to clean and disinfect.

2.) One of the 2 common resident shower/bath rooms contained a 2 by 4 inch hole in the floor at the whirlpool drain, and exposed an empty cavern of rock and concrete.

3.) Two of the 15 residents' bathrooms, contained 3 to 4 inch tears in the vinyl flooring next to the toilets; thus producing a surface difficult to clean.

4.) One of the 15 residents' bathrooms, contained a brownish discoloration 1 foot in diameter around the toilet.

5.) One of the 15 residents' bathrooms, contained a sink with an open gap of 2 by 1/2 inch missing behind the facet.

6.) Two of the 24 residents' rooms, contained sections of chair rail, which lacked a finish, exposing bare wood; thus making a surface difficult to clean.

7.) The therapy room contained 48 square feet of floor tiles with black marring.

During this environmental tour, maintenance staff B explained the clients pull at the wall paper, "If they find a loose piece they will pick at it." Staff added, "I've glued it back down... They [the

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F 253	Continued From page 3 residents] just keep picking at it." The facility failed to provide a policy or procedure related to the maintenance and housekeeping services of the facility. The facility failed to provide housekeeping and maintenance services to maintain a sanitary and comfortable interior for the residents.	F 253		
F 323 SS=E	483.25(h) FREE OF ACCIDENT HAZARDS/SUPERVISION/DEVICES The facility must ensure that the resident environment remains as free of accident hazards as is possible; and each resident receives adequate supervision and assistance devices to prevent accidents. This REQUIREMENT is not met as evidenced by: The facility reported a census of 83 residents. Based of observation and interview, the facility failed to provide an environment free as possible from accident hazards on 2 of 2 halls in the facility. Findings included: - On 8/1/12 from 2:30 pm to 4:00 pm, an environmental tour of the facility, completed with maintenance staff B, and housekeeping staff C; in which staff acknowledged toilet bolts with rough threading exposed, which protruded 1 to 1 and 1/2 inches above the bases of the toilets, and lacked covers. These noted areas included; 1 of	F 323		

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F 323	Continued From page 4 14 resident shared bathrooms on the south resident hallway, and 9 of 15 resident shared bathrooms on the north resident hallway. This created potential accident hazards to the residents using these bathrooms. The facility failed to provide and maintain an environment as free as possible from accident hazards for the residents of the facility who used these 10 resident bathrooms.	F 323		
F 329 SS=E	483.25(l) DRUG REGIMEN IS FREE FROM UNNECESSARY DRUGS Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used in excessive dose (including duplicate therapy); or for excessive duration; or without adequate monitoring; or without adequate indications for its use; or in the presence of adverse consequences which indicate the dose should be reduced or discontinued; or any combinations of the reasons above. Based on a comprehensive assessment of a resident, the facility must ensure that residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.	F 329		

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This REQUIREMENT is not met as evidenced by:
The facility identified a census of 83 residents. The sample included 8 residents. Based on observation, interview and record review, the facility failed to identify and monitor 7 of 7 residents reviewed for unnecessary medications (#1, 15, 54, 74, 69, 91, and 17) for the adverse consequences associated with the administration of medications with black box warnings. The facility further failed to obtain timely physician ordered laboratory test to monitor the therapeutic effects of medication ordered for 1 resident #74.

Findings included:

- The clinical record for resident #1 revealed the facility admitted the resident on 10/4/05, with diagnoses which included schizoaffective disorder (a mental disorder characterized by recurring distortions and perception and disordered thinking), convulsions (disorder of the brain that results in uncontrolled abnormal body movements), and hypertension (high blood pressure).

Physician's orders revealed the following mediations with black box warnings:

Toprol XL (extended release) 25 milligrams each morning, ordered 10/25/06, for diagnosis of tachycardia (rapid heart rate).

The 2011 Lexi-Comp Drug Information Handbook for Nursing, 12th Edition, page 933-936, identified metoprolol (Toprol-XL), with the following black box warning: "Beta-blocker therapy should not be

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withdrawn abruptly (particularly in patients with Coronary Artery Disease), but gradually tapered over 1-2 weeks to avoid acute tachycardia, hypertension, and/or ischemia."

FazaClo, 200 milligrams, at 8:00 A.M.; 100 milligrams, at noon; and 300 milligrams, at bedtime, ordered 9/30/09, for diagnosis of schizoaffective disorder.

The 2011 Lexi-Comp Drug Information Handbook for Nursing, 12th Edition, pages 329-332 identified the medication clozapine (FazaClo), with the following black box warnings: "Significant risk of agranulocytosis, potentially life-threatening. Seizures have been associated with clozapine use in a dose-dependent manner. Fatalities due to myocarditis have been reported; highest risk in the first month of therapy, however later cases also reported. May cause orthostasis hypotension (with or without syncope)."

Depakene suspension 250 milligrams in 5 milliliters, administer 20 milliliters (1000 milligrams) at bedtime, ordered 5/12/08, for convulsions and schizoaffective disorder.

Depakene suspension 250 milligrams in 5 milliliters, administer 10 milliliters (500 milligrams) at 8:00 A.M., ordered 5/20/12 for convulsions and schizoaffective disorder.

The 2011 Lexi-Comp Drug Information handbook for Nursing, 12th Edition, pages 1465-1468, identified valporic acid (depakene), with the following black box warning: "Cases of life-threatening pancreatitis, occurring at the start of therapy of following years of use, have been

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reported in adults and children."

Review of the plan of care, dated 6/29/12, recorded that, "The resident received the following routine or PRN (as needed) based medications: Advair, salmeterol, depakene, FazaClo, ferrous sulfate, Haldol concentrate, Haldol tablet, hydrochlorothizaide, Lexapro, Toprol XL, and Tylenol. These medications have black box warnings."

However, the plan of care, dated 6/29/12, failed to identify the specific black box warning and revealed no plan to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings.

Review of the medication administration record (MAR), dated 7/1/12, identified these medications with black box warnings, however failed to reveal the specific black box warnings and/or monitoring of the adverse consequences associated with the administration of the medications.

Observation, on 8/2/12 at 7:30 A.M., revealed the independent ambulatory resident, approached the conference room and stated he/she had a "billion dollars and there was a tornado outside."

On 7/31/12 at 4:00 P.M., licensed nursing staff H, reported that black box warnings had really bad side effects of medications and the facility listed the side effects on the medication administration record (MAR).

On 7/31/12 at 4:00 P.M., direct care staff I, reported the black box warnings listed on the

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F 329	Continued From page 8 resident's MAR and on the care plan. On 7/31/12 at 4:15 P.M. administrative nursing staff A, reported a new corporate policy to change the care plans with black box warnings and adding the specific black box warnings to each medication on the care plan as the care plans come due. Prior to that, the facility just had a laminated sheet that identified the black box warning for each medication, but not specific to the resident. On 8/1/12 8:25 P.M. administrative nursing staff E, reported that the facility originally identified the individual medications on the plan of care with black box warnings but not the specific warning . Administrative nursing staff E confirmed the black box warning not on the care plan. Administrative nursing staff E reported the pharmacy consultant attends the Quality Assurance meetings and provided the facility a general list of side effects associated with black box warnings. On 8/1/12 at 9:45 A.M., licensed nursing consultant G, reported that the corporation had not implemented any changes yet, the plan was on hold. Administrative nursing staff G confirmed that the facility needed to have a system to monitor side effects of medications with black box warnings. On 8/1/12 at 4:15 P.M., consultant pharmacist staff F, acknowledged several recommendations to the facility to add the specific black box warning to the medications on the plan of care. Not aware the facility was making the residents' care plans non-specific regarding black box warnings.	F 329		

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F 329	Continued From page 9 On 8/1/12 at 4:00 P.M., administrative nursing staff A, reported the facility lacked a policy for medications with black box warnings. The facility lacked a policy to direct staff to identify the specific medications on the resident's plan of care or to identify the specific adverse side effects of the medications. The facility failed to identify and monitor the resident for adverse consequences associated with the administration of these medications with black box warnings for this resident. - The clinical record for resident #15, revealed the facility admitted the resident on 10/21/09, with diagnoses which included schizoaffective disorder (a mental disorder characterized by recurring distortions and perception and disordered thinking), and diabetes mellitus type 2 (uncontrolled blood sugar levels), Physician's orders revealed the following medications with black box warnings: Depakene suspension (valproate sodium), 250 milligrams in 5 milliliters, give 500 milligrams (10 cubic centimeters), twice daily, ordered 4/28/11, for diagnosis of schizoaffective disorder. The 2011 Lexi-Comp Drug Information handbook for Nursing, 12th Edition, page 1465-1468, identified valproic acid (depakene), with the following black box warning: "Cases of life-threatening pancreatitis, occurring at the start of therapy or following years of use, have been	F 329		

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reported in adults and children."

Glucophage (Metformin), 1000 milligrams, twice daily with meals, ordered 11/4/10, for diagnosis of for diabetes mellitus type 2.

The 2011 Lexi-Comp Drug Information Handbook for Nursing, 12th Edition, page 905, identified the medication Glucophage (metformin), with the following black box warning: "Lactic acidosis is a rare, but potentially severe consequence of therapy with metformin."

Ibuprofen, 600 milligrams, every 4 hours with food PRN (as needed), ordered 8/18/10, for diagnosis of pain.

The 2011 Lexi-Comp Drug Information handbook for Nursing, 12th Edition, page 721, identified the medication ibuprofen, with the following black box warning: "NSAIDs (non-steriodal anti-inflammatory drugs) are associated with an increased risk of adverse cardiovascular thrombotic events, including fatal MI and stroke. NSAIDs may increase risk of gastrointestinal irritation, inflammation, ulceration, bleeding, and perforation."

Ritalin (Methylphenidate) 15 milligrams, twice daily, at 8 A.M. and Noon, dated 8/4/10, for schizoaffective disorder.

The 2011 Lexi-Comp Drug Information Handbook for Nursing,12th Edition, page 922-923, identified Ritalin with the following black box warning: "Potential for drug dependency exists - avoid abrupt discontinuation in patients who have received for prolonged periods."

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F 329	Continued From page 11 Review of the plan of care, dated 7/24/12, recorded, "The resident received the following medications on either a routine or PRN (as needed) basis: Actos, Aspirin (NSAID), Celexa, Depakene suspension, Geodon, Glucophage, Ritalin, Synthroid, Trazodone, Vasotec, Risperdal Consta, Ibuprofen, Tylenol and Zyprexa Zydis. These medications have black box warnings." However, the plan of care, dated 7/24/12, failed to identify the specific black box warning and revealed no plan to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings. Review of the medication administration record (MAR), dated 7/1/12, identified these medications with black box warnings, however failed to reveal the specific black box warnings and/or monitoring of the adverse consequences associated with the administration of the medications. Review of the Pharmacy Consultant Reports revealed: On 1/30/12, "One of the three most prevalent areas of focus dealt with 1) clinical monitoring, 2) Black Box Warning and 3) Diagnosis. System focus concerns identified; The specific medications that have black box warnings are listed in each client's care plan, but the statement concerning these may be too generic for future state survey. Not all black box warnings pertain to side effects. Recommendation for Action: Update care plans to include specific black box warnings for each medication. Will meet with the director of nursing and quality assurance next month."	F 329		

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F 329	Continued From page 12 On 2/29/12, "The care center's follow up of last visits recommendations was determined to be 19%. Focus areas: please follow up on communications - I need to see response to reconcile. 1) F-tag focus - behavior monitoring and 2) Quality Assurance Committee Meeting - black box warnings - discussed. Exited with the director of nursing." On 5/31/12, The Three most prevalent areas of focus dealt with: 1. black box warning 2) clinical monitoring and 3) drug-drug interaction." Observation, on 7/31/12 at 2:00 P.M. revealed the resident stood at the main nursing desk and asked for Scotch tape and then the resident placed the tape on the temples of his/her glasses. On 7/31/12 at 4:00 P.M., licensed nursing staff H, reported that black box warnings had really bad side effects of medications and the facility listed the side effects on the medication administration record (MAR). On 7/31/12 at 4:00 P.M., direct care staff I, reported the black box warnings listed on the resident's MAR and on the care plan. On 7/31/12 at 4:15 P.M. administrative nursing staff A reported a new corporate policy to change the care plans with black box warnings and adding the specific black box warnings to each medication on the care plan as the care plans come due. Prior to that, the facility just had a laminated sheet that identified the black box warning for each medication, but not specific to the resident.	F 329		

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F 329	Continued From page 13 On 8/1/12 8:25 P.M. administrative nursing staff E reported that the facility originally identified the individual medications on the plan of care with black box warnings but not the specific warning . Administrative nursing staff E confirmed the black box warning not on the care plan. Administrative nursing staff E reported the pharmacy consultant attends the Quality Assurance meetings and provided the facility a general list of side effects associated with black box warnings. On 8/1/12 at 9:45 A.M., licensed nursing consultant G, reported that the corporation had not implemented any changes yet, the plan was on hold. Administrative nursing staff G confirmed that the facility needed to have a system to monitor side effects of medications with black box warnings. On 8/1/12 at 4:15 P.M., consultant pharmacist staff F, acknowledged several recommendations to the facility to add the specific black box warning to the medications on the plan of care. Not aware the facility was making the residents' care plans non-specific regarding black box warnings. On 8/1/12 at 4:00 P.M., administrative nursing staff A, reported the facility lacked a policy for medications with black box warnings. The facility lacked a policy to direct staff to identify the specific medications on the resident's plan of care or to identify the specific adverse side effects of the medications. The facility failed to identify and monitor the	F 329		

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resident for adverse consequences associated with the administration of these medications with black box warnings.

- The clinical record for resident #54 with diagnoses which included: paranoid schizophrenia,(a type of chronic mental illness in which a person loses touch with reality. They are unable to tell the difference between what is real and not real, unable to think clearly, and will often hear voices).

Physician's orders revealed the following medications with BBW (black box warnings):

Haldol, 1 milligram, by mouth, every evening at bedtime, ordered 6/1/12, for diagnosis of schizophrenia.

The 2011 Lexi-Comp Drug Information Handbook for Nursing, page 694, identified Haldol with the black box warning: "May be inappropriate for increased risk of death. Not approved for the treatment of dementia related psychosis, prolong QT interval, life threatening arrhythmia, may occur. May cause anticholeringic effects, may be sedating or cause extrapyridmal symptoms."

Naproxen, 220 milligrams, by mouth, PRN (as needed), ordered 4/12/2012, with food, as needed for pain.

The MARs (medication administration records) from April through July, 2012, revealed the medication administered to the resident 1 time in July 2012, not administered in June 2012, administered 4 times in May 2012, and 1 time in

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April 2012.

The 2011 Lexi-Comp Drug Information Handbook for Nursing, page 721, identified the following black box warning: "NSAIDs (nonsteroidal anti-inflammatory drug) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms

Review of the plan of care, dated 7/7/2012, revealed no plan to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings.

The current July, 2012, MAR listed the medications with black box warnings with some side effects, but failed to identify the specific BBW for the medication, and failed to identify necessary monitoring for adverse consequences associated with the medications.

On 7/31/12 at 2:45 PM, observation revealed the resident sat in his/her room and stated, "I have dentures, they fit okay," then the resident went outside to smoke.

On 8/1/12 at 12:10 PM, observation revealed the resident eating lunch in the dining room without

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F 329	Continued From page 16 difficulty. Interview on 7/13/12 at 4:00 PM, licensed nursing staff H reported black box warnings were effects of medications and the facility listed the really bad side side effects on the medication administration record. On 7/31/12 at 4:00 PM, direct care staff I , reported the black box warnings as listed on the resident's MAR, and on the care plan and that the facility staff must go look them up. On 8/1/12 at 8:25 AM, interview with licensed administrative staff F revealed, "We were originally putting the medications on the care plan and identifying that they have a BBW but not putting the specific warning on the care plan. The BBW is not on the care plan. The pharmacy consultant comes to the QA (quality assurance) meeting and has given the facility a general list of medication side effects." On 8/1/12 at 9:45 AM, consultant licensed nursing staff G reported, "The corporation has not made any changes yet related to monitoring for black box warnings, the plan is on hold. The facility needs to have a system to monitor for black box warnings." On 8/1/12 at 4:00 PM, administrative nursing staff A stated, "The facility does not have a policy for black box warnings." The facility failed to identify and monitor the resident for adverse consequences associated with the administration of these medications with black box warnings.	F 329		

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- The clinical record of resident #74 revealed the resident admitted to the facility on 2/24/2010, with diagnoses which included schizopheneric disorder (A mental illness that makes it hard to tell the difference between what is real and what is not real, and to think clearly.)

Physician's orders revealed the following medications with BBW (black box warnings):

Lithium Carbonate, 600 milligrams, daily at bedtime, ordered 2/24/2012, and 900 milligrams, daily every morning, ordered 2/25/2012, for diagnosis of schizopheneric disorder.

The 2011 Lexi-Comp Drug Information Handbook for Nursing , page 861 identified Lithium Carbonate with the following black box warning : "Lithium toxicity is closely related to serum levels and can occur at therapeutic doses: serum lithium determinations are anticholeringic effects, may be sedating or cause extrapyridmal symptoms."

Review of the 5/23/12, care plan identified the resident received routine /PRN (as needed) medications. The care plan documented, "These medication have black box warnings. Please refer to the resident's MAR [medication administration record] for potential adverse side effects required to monitor therapy."

Haldol Deconate, 200 milligrams, IM (intramuscularly) injection, every 28 days , ordered 2/3/2011, for schizopheneric disorder.

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The 2011 Lexi-Comp Drug Information Handbook for Nursing, page 694, identified Haldol with the black box warning: "May be inappropriate for increased risk of death. Not approved for the treatment of dementia related psychosis, prolong QT interval, life threatening arrhythmia, may occur. May cause effects."

The current July, 2012, MAR (medication administration record) listed the medications with black box warnings with some side effects, but failed to identify the specific BBW for the medication, and failed to identify necessary monitoring for adverse consequences associated with the medications.

On 7/31/12 at 1:50 PM, observation revealed the resident walked from the commons area to his/her room.

On 7/31/12 at 4:00 PM, direct care staff I , reported the black box warnings listed on the resident's MAR and on the care plan.

On 8/1/12 at 8:25 AM, interview with licensed administrative staff F revealed, "We were originally putting the medications on the care plan and identifying that that they have a BBW but not putting the specific warning on the care plan. The BBW is not on the care plan. The pharmacy consultant comes to the QA (quality assurance) meeting and has given the facility a general list medication side effects."

On 8/1/12 at 9:45 AM, consultant licensed nursing staff G reported, "The corporation has not made any changes yet related to monitoring for black box warnings, the plan is on hold. The

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facility needs to have a system to monitor for black box warnings."

On 8/1/12 at 4:00 PM, administrative nursing staff A stated, "The facility does not have a policy for black box warnings."

The facility failed to identify and monitor the resident for adverse consequences associated with the administration of these medications with black box warnings.

Furthermore, the 5/2/12, physician order, documented for the staff to administer synthroid, 25 meq.(milliequilvalents), by mouth, daily.

On 8/1/12 at 1:30 PM, review of the medical record for the resident, revealed the 5/2/12, laboratory result sheet for T4 and TSH (thyroid testing) with a physician order to test these again in 6 weeks. Further review of the clinical record revealed a lack of laboratory test results corresponding to this date, included in the medical record.

On 8/1/12 at 1:45 PM, licensed nursing staff J, verified the resident's medical record contained the physician order to test the resident's T4 and TSH laboratory test in 6 weeks. Staff J stated, "You will have to check medical records if it was completed."

On 8/1/12 at 2:17 PM, licensed nursing staff K explained, " I didn't see the order on the lab sheet. That lab has not been done yet, it was scheduled for the 1st part of August. I have moved it up since finding the order on the lab sheet, I have it scheduled for tomorrow."

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The facility failed to complete the physician order laboratory testing to ensure adequate medication monitoring and therapeutic effect of the medication for this resident.

- The clinical record for resident #69, revealed the resident admitted to the facility on 8/19/2008, with diagnoses which including; bipolar disorder (a condition in which people go back and forth between periods of a very good or irritable mood).

Physician's orders, revealed the following medications with a black box warning;

Lithium Carbonate, 300 mg (milligrams), two times daily, ordered 12/12/08, for diagnosis of bipolar disorder.

The 2011, 16th Edition, Lexi-Comp's Geriatric Drug Handbook, page 1025, identified the following black box warning: "Lithium toxicity is closely related to serum levels and can occur at therapeutic doses; serum lithium determinations are required to monitor therapy."

Review of the plan of care, dated on 7/24/12, revealed the resident received the following medication on a routine basis: lithium carbonate. However the care plan lacked the specific information related to the monitoring of the adverse associated with the administration with these medications with black box warnings.

Review of the medication administration record (MAR), dated July, 2012, failed to identify these medications with black box warnings and failed to reveal the specific black box warning and

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monitoring of adverse consequences associated with the administration of the medications.

On 7/31/12 at 3:30 PM, the resident ambulated in the hall, and the resident's gait remained steady.

On 7/31/12 at 4:00 PM, licensed nursing staff H reported, "Black box warnings are really bad side effects of the medication. The side effects are listed on the MAR."

On 7/31/12 at 4:00 PM, direct care staff I reported, " Black box warnings are listed on the MAR and on the care plan. I have to look them up on the care plan."

On 7/31/12 at 4:15 PM, licensed administrative staff A reported," I just received a new corporate policy to change the care plans with BBW (black box warning). We are adding the specific BBW to the care plans as they come due. Prior to this we just had a laminated sheet that identified the BBW for each medication, but not specific to the resident. However the facility failed to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings."

On 8/1/12 8:25 AM, licensed administrative nursing staff E reported, " We originally identified the medications on the plan of care and identified they had a BBW, but not putting the specific warning on the care plan."

On 8/1/12 9:45 AM, licensed nursing consultant staff G reported, " The corporation has not implemented any changes yet and the plan is on hold. Furthermore, staff C confirmed the facility

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needs to have a system to monitor side effects for black box warnings."

On 8/1/12 at 4:00 PM, licensed administrative staff A reported, " I do not have a policy for black box warnings."

On 8/1/12 at 4:15 PM, pharmacy consultant F reported, "I have recommended several times to the facility to add the specific black box warnings to the medications on the plan of care... I was not aware the facility was making the resident's care plans non-specific regarding BBW."

The facility failed to identify and monitor the resident for the adverse consequences associated with the administration of these medications with black box warning.

- The clinical record of resident #91, revealed the resident admitted to the facility on 2/20/12, with the following diagnoses which included; schizoaffective disorder (a mental disorder characterized by recurring distortions in perception and disordered thinking), and hypertension (high blood pressure).

The physician orders revealed the following medications with Black Box Warning :

Clozaril, 200 mg (milligrams), two times daily, ordered 2/20/12, for diagnoses of schizoaffective disorder.

The 2011 Lexi-Comp's Geriatric Dosage Handbook,16th Edition, page 380-381, identified Clozapine (Clozaril) with the following black box

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warning: "Significant risk of agranulocytosis, potentially life-threatening. Seizures have been associated with clozapine use in a dose-dependent manner. Fatalities due to myocarditis have been reported; highest risk in the first month of therapy, however, later cases also reported. May cause orthostatic hypotension (with or without syncope)."

Triamterene/ hydrochlorathiazied, 37.5 mg/25 mg, in the morning, ordered on 2/20/12, for diagnoses of hypertension.

The 2011 Lexi-Comp's,16th Edition,Geriatric Dosage Handbook, page 1806, identified Triamterene with the following black box warning:" Hyperkalemia can occur; patients at risk include those with renal impairment, diabetes, the elderly, and the severely ill. Serum potassium levels must be monitored at frequent intervals especially when dosages are changed or with any illness that may cause renal dysfunction."

Depakote, 750 mg, in the morning, and 1000 mg at bedtime, ordered on 2/20/12, for diagnoses of schizoaffective disorder.

The 2011 Lexi-Comp's Drug Reference Geriatric Dosage Handbook,16th Edition, page 509 identified Depakote with the following black box warning: "Hepatic failure resulting in fatalities has occurred in patients. Cases of life-threatening pancreatitis, occurring at the start of therapy or following years of use, have been reported."

Naproxen, 375 mg, twice daily with food, for three weeks, ordered on 7/11/12, with a stop date of

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F 329	Continued From page 24 7/31/12, for diagnosis of pain. The 2011,16th Edition, Lexi-Comp's Geriatric Dosage Handbook page 1213, identified Naproxen: with the following black box warning:" NSAIDs (nonsteroidal anti-inflamatory drug) may increase risk of gastrointestinal irritation, inflammation, ulceration, bleeding, and perforation. NSAIDs are associated with an increased risk of adverse cardiovascular thrombotic events, including and myocardial infarction and a stroke." Review of the plan of care, dated 5/29/12, revealed the resident received the following medications on either a routine or PRN (as needed) basis: clozaril, depakote, Naproxen, and triamterene/hydrochlorathiazide. However the care plan lacked the specific information related to the monitoring of the adverse associated with the administration with these medications with black box warning. Review of the medication administration record (MAR), dated July 2012, revealed the following medications with a black box warning; triamterene/hydrochlorithiazide, prolixin, naproxen, clozaril, depakote and tylenol. However the facility failed in monitoring of the adverse consequences associated with their administration. Observation on, 8/1/12 at 11:45 AM, the resident ambulated in the hall, by self. The resident's gait remained steady, and without any Parkinson type symptoms noted. On 7/31/12 at 4:00 PM, licensed nursing staff H	F 329		

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reported, "Black box warnings are really bad side effects of the medication. The side effects are" listed on the MAR.

On 7/31/12 at 4:00 PM, direct care staff I reported, "Black box warnings are listed on the MAR and on the care plan. I have to look them up on the care plan."

On 7/31/12 at 4:15 PM, licensed administrative staff A reported," I just received a new corporate policy to change the care plans with BBW (black box warning). We are adding the specific BBW to the care plans as they come due. Prior to this we just had a laminated sheet that identified the BBW for each medication, but not specific to the resident. However the facility failed to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings."

On 8/1/12 8:25 AM, licensed administrative nursing staff E reported, " We originally identified the medications on the plan of care and identify they have a BBW, but not putting the specific warning on the care plan."

On 8/1/12 9:45 AM, licensed nursing consultant staff G reported, "The corporation has not implemented any changes yet and the plan is on hold. Furthermore, staff confirmed the facility needs to have a system to monitor side effects for black box warnings."

On 8/1/12 at 4:00 PM, licensed administrative staff A reported, "I do not have a policy for black box warnings."

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F 329	Continued From page 26 On 8/1/12 at 4:15 PM, licensed pharmacy consultant F reported, " I have recommended several times to the facility to add the specific black box warning to the medications on the plan of care. ..I was not aware the facility was making the resident's care plans non-specific regarding BBW" The facility failed to identify and monitor the resident for the adverse consequences associated with the administration of these medications with black box warning. - A review of resident # 17's face sheet, medical record revealed an admission date of 8/29/96, with diagnoses which included: schizophrenic disorders (a long term mental illness in which a person loses touch with reality). Physician's orders revealed the following medications with black box warnings: 1.) Depakene suspension, 250 mg (milligrams) per 5 ml (milliliters), give 30 ml, by mouth, at every bedtime, ordered on 10/20/07, for the diagnosis of schizophrenic disorders. The 2011 Geriatric Dosage Handbook, 16th edition, page 1836, identified the following black box warning for Depakene: [U.S. Boxed Warning]: "Hepatic failure resulting in fatalities has occurred in patients. Cases of life-threatening pancreatitis, occurring at the start of therapy or following years of use, have been reported in adults and children. " 2.) Fazaclo (Clozapine), by mouth, 300 mg, at 4:00 pm, and 600 mg, with every bedtime, ordered on 6/10/06, for the diagnosis of schizophrenic disorders.	F 329		

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The 2011 Geriatric Dosage Handbook, 16th edition, page 380 - 381, identified the following black box warning for Clozapine: [U.S. Boxed Warning]: " Significant risk of agranulocytosis, potentially life- threatening. Seizures have been associated with clozapine use in a dose-dependent manner. Fatalities due to myocarditis have been reported; highest risk in the first month of therapy, however, later cases also reported. May cause orthostatic hypotension (with or without syncope). "
Review of the plan of care, revised on 7/3/12, directed staff, "[The resident] receives the following medication on either a routine of PRN [as needed] basis: Depakene, Fazaclo, Risperdal, and Tylenol. These medications have a black box warning. Please be alert to the potential adverse effects/side effects listed on [his/her] MAR [medication administration record]."
However, the care plan lacked the specific information related to the monitoring of the adverse conquences associated with administration of these medications with black box warnings.

Review of the medication administration record, dated July 2012, failed to identify these medications with black box warnings and failed to reveal the specific black box warning and monitoring of adverse consequences associated with the administration of the medications.

On 7/31/12 at 2:19 pm, observation revealed the resident ambulated in a television room and paced in circles.

On 7/31/12 at 4:00 pm, licensed nursing staff H

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reported, "Black box warnings are really bad side effects of the medication. The side effects are listed on the MAR."On 7/31/12 at 4:00 pm, direct care staff I reported, "Black box warnings are listed on the MAR and on the care plan. I have to look them up on the care plan."

On 7/31/12 at 4:15 pm, licensed administrative staff A reported,"I just received a new corporate policy to change the care plans with BBW (black box warning). We are adding the specific BBW to the care plans as they come due. Prior to this we just had a laminated sheet that identified the BBW for each medication, but not specific to the resident. However, the facility failed to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings."

On 8/1/12 8:25 am, licensed administrative nursing staff E reported, "We originally identified the medications on the plan of care and identify they have a BBW, but not putting the specific warning on the care plan."

On 8/1/12 at 9:45 am, licensed nursing consultant staff G reported, "The corporation has not implemented any changes yet and the plan is on hold. Furthermore, staff confirmed the facility needs to have a system to monitor side effects for black box warnings."

On 8/1/12 at 4:00 pm, licensed administrative staff A reported, "I do not have a policy for black box warnings."

On 8/1/12 at 4:15 pm, pharmacy consultant F reported, "I have recommended several times to

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F 329	Continued From page 29 the facility to add the specific black box warning to the medications on the plan of care. ...I was not aware the facility was making the resident's care plans non-specific regarding BBW." The facility failed to identify and monitor the resident for the adverse consequences associated with the administration of these medications with black box warning.	F 329		
F 428 SS=E	483.60(c) DRUG REGIMEN REVIEW, REPORT IRREGULAR, ACT ON The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. The pharmacist must report any irregularities to the attending physician, and the director of nursing, and these reports must be acted upon. This REQUIREMENT is not met as evidenced by: The facility identified a census of 83 residents. The sample included 8 residents. Based on observation, interview and record review, the facility failed to ensure staff acted on pharmacy recommendations regarding monitoring adverse side effects for 7 of 7 residents reviewed for unnecessary medications (#1, 15, 54, 74, 69, 91, and 17) that received medications with black box warnings. The facility pharmacist failed to identify the lack of timely action on physician ordered laboratory test to monitor the therapeutic effects of medication ordered for 1 resident, #74.	F 428		

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Findings included:

- The clinical record for resident #1, revealed the facility admitted the resident on 10/4/05, with diagnoses which included schizoaffective disorder (a mental disorder characterized by recurring distortions and perception and disordered thinking), convulsions (disorder of the brain that results in uncontrolled abnormal body movements), and hypertension (high blood pressure).

Physician's orders revealed the following mediations with black box warnings:

Toprol XL (extended release), 25 milligrams, each morning, ordered 10/25/06, for diagnosis of tachycardia (rapid heart rate).

The 2011 Lexi-Comp Drug Information Handbook for Nursing, 12th Edition, page 933-936, identified metoprolol (Toprol-XL), with the following black box warning: "Beta-blocker therapy should not be withdrawn abruptly (particularly in patients with Coronary Artery Disease), but gradually tapered over 1-2 weeks to avoid acute tachycardia, hypertension, and/or ischemia."

FazaClo, 200 milligrams, at 8:00 A.M.; 100 milligrams, at noon; and 300 milligrams, at bedtime, ordered 9/30/09, for diagnosis of schizoaffective disorder.

The 2011 Lexi-Comp Drug Information Handbook for Nursing, 12th Edition, pages 329-332 identified the medication clozapine (FazaClo),

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with the following black box warnings: "Significant risk of agranulocytosis, potentially life-threatening. Seizures have been associated with clozapine use in a dose-dependent manner. Fatalities due to myocarditis have been reported; highest risk in the first month of therapy, however later cases also reported. May cause orthostasis hypotension (with or without syncope)."

Depakene suspension, 250 milligrams, in 5 milliliters, administer 20 milliliters (1000 milligrams) at bedtime, ordered 5/12/08, for convulsions and schizoaffective disorder.

Depakene suspension, 250 milligrams, in 5 milliliters, administer 10 milliliters (500 milligrams) at 8:00 A.M., ordered 5/20/12 for convulsions and schizoaffective disorder.

The 2011 Lexi-Comp Drug Information handbook for Nursing, 12th Edition, pages 1465-1468, identified valproic acid (depakene), with the following black box warning: "Cases of life-threatening pancreatitis, occurring at the start of therapy of following years of use, have been reported in adults and children."

Review of the plan of care, dated 6/29/12, recorded, "The resident received the following routine or PRN (as needed) based medications: Advair, salmeterol, depakene, FazaClo, ferrous sulfate, Haldol concentrate, Haldol tablet, hydrochlorothizaide, Lexapro, Toprol XL, and Tylenol. These medications have black box warnings."

However, the plan of care, dated 6/29/12, failed to identify the specific black box warning and

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revealed no plan to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings.

Review of the medication administration record (MAR), dated 7/1/12, identified these medications with black box warnings, however failed to reveal the specific black box warnings and/or monitoring of the adverse consequences associated with the administration of the medications.

Observation, on 8/2/12 at 7:30 A.M., revealed the independent ambulatory resident, approached the conference room and stated he/she had a "billion dollars and there was a tornado outside."

On 7/31/12 at 4:00 P.M., licensed nursing staff H, reported that black box warnings had really bad side effects of medications and the facility listed the side effects on the medication administration record (MAR).

On 7/31/12 at 4:00 P.M., direct care staff I, reported the black box warnings listed on the resident's MAR and on the care plan.

On 7/31/12 at 4:15 P.M. administrative nursing staff A, reported a new corporate policy to change the care plans with black box warnings and adding the specific black box warnings to each medication on the care plan as the care plans come due. Prior to that, the facility just had a laminated sheet that identified the black box warning for each medication, but not specific to the resident.

On 8/1/12 8:25 P.M. administrative nursing staff

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E, reported that the facility originally identified the individual medications on the plan of care with black box warnings but not the specific warning . Administrative nursing staff E confirmed the black box warning not on the care plan. Administrative nursing staff E reported the pharmacy consultant attends the Quality Assurance meetings and provided the facility a general list of side effects associated with black box warnings.

On 8/1/12 at 9:45 A.M., licensed nursing consultant G, reported that the corporation had not implemented any changes yet, the plan was on hold. Administrative nursing staff G confirmed that the facility needed to have a system to monitor side effects of medications with black box warnings.

On 8/1/12 at 4:15 P.M., consultant pharmacist staff F, acknowledged several recommendations to the facility to add the specific black box warning to the medications on the plan of care. Not aware the facility was making the residents' care plans non-specific regarding black box warnings.

On 8/1/12 at 4:00 P.M., administrative nursing staff A, reported the facility lacked a policy for medications with black box warnings.

The facility lacked a policy to direct staff to identify the specific medications on the resident's plan of care or to identify the specific adverse side effects of the medications.

The facility failed to follow the consultant pharmacy recommendations to identify medications with applicable Black Box Warnings,

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to ensure staff monitored potential adverse consequences associated with the administration of Toprol XL, FazaClo and Depakene suspension for this resident.

- The clinical record for resident #15, revealed the facility admitted the resident on 10/21/09, with diagnoses which included schizoaffective disorder (a mental disorder characterized by recurring distortions and perception and disordered thinking), and diabetes mellitus type 2 (uncontrolled blood sugar levels),

Physician's orders revealed the following medications with black box warnings:

Depakene suspension (valproate sodium), 250 milligrams in 5 milliliters, give 500 milligrams (10 cubic centimeters), twice daily, ordered 4/28/11, for diagnosis of schizoaffective disorder.

The 2011 Lexi-Comp Drug Information handbook for Nursing, 12th Edition, page 1465-1468, identified valproic acid (depakene), with the following black box warning: "Cases of life-threatening pancreatitis, occurring at the start of therapy or following years of use, have been reported in adults and children."

Glucophage (Metformin), 1000 milligrams, twice daily with meals, ordered 11/4/10, for diagnosis of for diabetes mellitus type 2.

The 2011 Lexi-Comp Drug Information Handbook for Nursing, 12th Edition, page 905, identified the medication Glucophage (metformin), with the following black box warning: "Lactic acidosis is a

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rare, but potentially severe consequence of therapy with metformin."

Ibuprofen, 600 milligrams, every 4 hours with food PRN (as needed), ordered 8/18/10, for diagnosis of pain.

The 2011 Lexi-Comp Drug Information handbook for Nursing, 12th Edition, page 721, identified the medication ibuprofen, with the following black box warning: "NSAIDs (non-steriodal anti-inflammatory drugs) are associated with an increased risk of adverse cardiovascular thrombotic events, including fatal MI and stroke. NSAIDs may increase risk of gastrointestinal irritation, inflammation, ulceration, bleeding, and perforation."

Ritalin (Methylphenidate) 15 milligrams, twice daily, at 8 A.M. and Noon, dated 8/4/10, for schizoaffective disorder.

The 2011 Lexi-Comp Drug Information Handbook for Nursing,12th Edition, page 922-923, identified Ritalin with the following black box warning: "Potential for drug dependency exists - avoid abrupt discontinuation in patients who have received for prolonged periods."

Review of the plan of care, dated 7/24/12, recorded, "The resident received the following medications on either a routine or PRN (as needed) basis: Actos, Aspirin (NSAID), Celexa, Depakene suspension, Geodon, Glucophage, Ritalin, Synthroid, Trazodone, Vasotec, Risperdal Consta, Ibuprofen, Tylenol and Zyprexa Zydis. These medications have black box warnings."

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However, the plan of care, dated 7/24/12, failed to identify the specific black box warning and revealed no plan to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings.

Review of the medication administration record (MAR), dated 7/1/12, identified these medications with black box warnings, however failed to reveal the specific black box warnings and/or monitoring of the adverse consequences associated with the administration of the medications.

Review of the Pharmacy Consultant Reports revealed:
On 1/30/12, "One of the three most prevalent areas of focus dealt with 1) clinical monitoring, 2) Black Box Warning and 3) Diagnosis. System focus concerns identified; The specific medications that have black box warnings are listed in each client's care plan, but the statement concerning these may be too generic for future state survey. Not all black box warnings pertain to side effects. Recommendation for Action: Update care plans to include specific black box warnings for each medication. Will meet with the director of nursing and quality assurance next month."

On 2/29/12, "The care center's follow up of last visits recommendations was determined to be 19%. Focus areas: please follow up on communications - I need to see response to reconcile. 1) F-tag focus - behavior monitoring and 2) Quality Assurance Committee Meeting - black box warnings - discussed. Exited with the director of nursing."

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F 428	Continued From page 37 On 5/31/12, The Three most prevalent areas of focus dealt with: 1. black box warning 2) clinical monitoring and 3) drug-drug interaction." Observation on 7/31/12 at 2:00 P.M. revealed the resident stood at the main nursing desk asked for Scotch tape and placed the tape on the temples of his/her glasses. On 7/31/12 at 4:00 P.M., licensed nursing staff H, reported that black box warnings had really bad side effects of medications and the facility listed the side effects on the medication administration record (MAR). On 7/31/12 at 4:00 P.M., direct care staff I, reported the black box warnings listed on the resident's MAR and on the care plan. On 7/31/12 at 4:15 P.M. administrative nursing staff A reported a new corporate policy to change the care plans with black box warnings and adding the specific black box warnings to each medication on the care plan as the care plans come due. Prior to that, the facility just had a laminated sheet that identified the black box warning for each medication, but not specific to the resident. On 8/1/12 8:25 P.M. administrative nursing staff E reported that the facility originally identified the individual medications on the plan of care with black box warnings but not the specific warning . Administrative nursing staff E confirmed the black box warning not on the care plan. Administrative nursing staff E reported the pharmacy consultant attends the Quality Assurance meetings and provided the facility a general list of side effects	F 428		

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associated with black box warnings.

On 8/1/12 at 9:45 A.M., licensed nursing consultant G, reported that the corporation had not implemented any changes yet, the plan was on hold. Administrative nursing staff G confirmed that the facility needed to have a system to monitor side effects of medications with black box warnings.

On 8/1/12 at 4:15 P.M., consultant pharmacist staff F, acknowledged several recommendations to the facility to add the specific black box warning to the medications on the plan of care. Not aware the facility was making the residents' care plans non-specific regarding black box warnings.

On 8/1/12 at 4:00 P.M., administrative nursing staff A, reported the facility lacked a policy for medications with black box warnings.

The facility lacked a policy to direct staff to identify the specific medications on the resident's plan of care or to identify the specific adverse side effects of the medications.

The facility failed to follow the consultant pharmacy recommendations to identify medications with applicable Black Box Warnings, to ensure staff monitored potential adverse consequences associated with the administration of Depakene suspension, Glucophage, ibuprofen and Ritalin for this resident.

The clinical record for resident #54 included diagnoses: paranoid schizophrenia,(a type of

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chronic mental illness in which a person loses touch with reality. They are unable to tell the difference between what is real and not real, unable to think clearly, and will often hear voices).

Physician's orders revealed the following medications with BBW (black box warnings):

Haldol, 1 milligram, by mouth, every evening at bedtime, ordered 6/1/12, for diagnosis of schizophrenia

The 2011 Lexi-Comp Drug Information Handbook for Nursing, page 694, identified Haldol with the black box warning: "May be inappropriate for increased risk of death. Not approved for the treatment of dementia related psychosis, prolong QT interval, life threatening arrhythmia, may occur. May cause anticholeringic effects, may be sedating or cause extrapyridmal symptoms."

Naproxen, 220 milligrams, by mouth, PRN (as needed) ordered 4/12/2012, with food, as needed for pain.

The MARs (medication administration records) from April, 2012 through July, 2012, documented the facility staff administered the Naproxen medication to the resident 1 time in July, 2012, none administered in June, 2012, 4 times administered in May, 2012, and 1 time administered in April, 2012.

The 2011 Lexi-Comp Drug Information Handbook for Nursing, page 721, identified the following black box warning: "NSAIDs (nonsteroidal anti-inflammatory drug) may cause an increased risk of serious cardiovascular thrombotic events,

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myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms."

Review of the plan of care, dated 7/7/2012, revealed no plan to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings.

The current July, 2012, MAR listed the medications with black box warnings with some side effects, but failed to identify the specific BBW for the medication, and failed to identify necessary monitoring for adverse consequences associated with the medications.

On 7/31/12 at 2:45 PM, observation revealed the resident sat in his/her room, and stated, "I have dentures, they fit okay," then the resident went outside to smoke.

On 8/1/12 at 12:10 PM, observation revealed the resident eating lunch in the dining room without difficulty.

Interview on 7/13/12 at 4:00 PM, licensed nursing staff H reported that black box warnings were effects of medications and the facility listed the really bad side side effects on the medication administration record.

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F 428	Continued From page 41 On 7/31/12 at 4:00 PM, direct care staff I , reported the black box warnings listed on the resident's MAR, and the care plan and staff must look them up. On 8/1/12 at 8:25 AM, interview with licensed administrative staff F revealed, "We were originally putting the medications on the care plan and identifying that that they have a BBW but not putting the specific warning on the care plan. The BBW is not on the care plan. The pharmacy consultant comes to the QA (quality assurance) meeting and has given the facility a general list of medication side effects." On 8/1/12 at 9:45 AM, consultant licensed nursing staff G reported, " The corporation has not made any changes yet related to monitoring for black box warnings, the plan is on hold. The facility needs to have a system to monitor for black box warnings." On 8/1/12 at 4:00 PM, administrative nursing staff A stated, "The facility does not have a policy for black box warnings." On 8/1/12 at 4:15 PM, pharmacy consultant F reported, " I have recommended several times to the facility to add the specific black box warning to the medications on the plan of care... I was not aware the facility was making the resident's care plans non-specific regarding BBW." The facility failed to follow the consultant pharmacist recommendations to identify medications with applicable Black Box Warnings, to ensure staff monitored potential adverse	F 428		

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consequences associated with the administration of Haldol, and Naproxen for this resident.

- The clinical record of resident #74 revealed the resident admitted to the facility on 2/24/2010, with diagnoses which included schizopheneric disorder.(A mental illness that makes it hard to tell the difference between what is real and what is not real, and to think clearly.)

Physician's orders revealed the following medications with black box warnings:

Lithium Carbonate, 600 milligrams, daily at bedtime, ordered 2/24/2012, and 900 milligrams, daily every morning, ordered 2/25/2012, for diagnosis of schizopheneric disorder.

The 2011 Lexi-Comp Drug Information Handbook for Nursing , page 861 identified Lithium Carbonate with the following black box warning : "Lithium toxicity is closely related to serum levels and can occur at therapeutic doses: serum lithium determinations are anticholeringic effects, may be sedating or cause extrapyridmal symptoms."

Review of the 5/23/12, care plan identified the resident received routine /PRN medications. The care plan documented, "These medication have black box warnings. Please refer to the resident's MAR for potential adverse side effects required to monitor therapy."

Haldol Deconate, 200 milligrams, IM (intramuscularly) injection, every 28 days, ordered 2/3/2011, for schizopheneric disorder.

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The 2011 Lexi-Comp Drug Information Handbook for Nursing, page 694, identified Haldol with the black box warning: "May be inappropriate for increased risk of death. Not approved for the treatment of dementia related psychosis, prolong QT interval, life threatening arrhythmia, may occur. May cause effects."

The current July, 2012, MAR (medication administration record) listed the medications with black box warnings with some side effects, but failed to identify the specific BBW for the medication, and failed to identify necessary monitoring for adverse consequences associated with the medications.

On 7/31/12 at 1:50 PM, observation revealed the resident walked from the commons area to his/her room.

On 7/31/12 at 4:00 PM, direct care staff I , reported the black box warnings as listed on the resident's MAR and on the care plan.

On 8/1/12 at 8:25 AM, interview with licensed administrative staff F revealed, "We were originally putting the medications on the care plan and identifying that that they have a BBW (Black Box Warning) but not putting the specific warning on the care plan. The BBW is not on the care plan. The pharmacy consultant comes to the QA (quality assurance) meeting and has given the facility a general list medication side effects."

On 8/1/12 at 9:45 AM, consultant licensed nursing staff G reported, " The corporation has not made any changes yet related to monitoring for black box warnings, the plan is on hold. The

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facility needs to have a system to monitor for black box warnings"

On 8/1/12 at 4:00 PM, administrative nursing staff A stated, "The facility does not have a policy for black box warnings."

Furthermore, the 5/2/12 physician order, documented Synthroid 25 meq. (milliequilvalents), by mouth daily.

On 8/1/12 at 1:30 PM, review of the medical record for the resident, revealed the 5/2/12, laboratory result for T4 and TSH (thyroid testing) with a physician order to test again in 6 weeks. Further review of the clinical record revealed a lack of lab test results corresponding to this date included in the medical record.

On 8/1/12 at 1:45 PM, licensed nursing staff J, verified the resident's medical record with an order for T4 and TSH laboratory to retest in 6 weeks. Licensed nursing staff J stated, "You will have to check medical records if it was completed."

On 8/1/12 at 2:17 PM, licensed nursing staff K explained, " I didn't see the order on the lab sheet. That lab has not been done yet, it was scheduled for the 1st part of August. I have moved it up since finding the order on the lab sheet. I have it scheduled for tomorrow."

On 8/1/12 at 4:15 PM, pharmacy consultant F reported, " I have recommended several times to the facility to add the specific black box warning to the medications on the plan of care... I was not aware the facility was making the resident's care

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F 428	Continued From page 45 plans non-specific regarding BBW." The facility failed to follow the consultant pharmacist recommendations to identify medications with applicable Black Box Warnings, to ensure staff monitored potential adverse consequences associated with the administration of Lithium Carbonate, and Haldol Deconate, for this resident and failed to identify the facility lack of timely action on the physician ordered laboratory test, to monitor the therapeutic effects of medications ordered for this resident. - The clinical record for resident #69, revealed the resident admitted to the facility on 8/19/2008, with diagnoses which including; bipolar disorder (a condition in which people go back and forth between periods of a very good or irritable mood). Physician's orders, revealed the following medications with a black box warning; Lithium Carbonate, 300 mg (milligrams), two times daily, ordered 12/12/08, for diagnosis of bipolar disorder. The 2011, 16th Edition, Lexi-Comp's Geriatric Drug Handbook, page 1025, identified the following black box warning: "Lithium toxicity is closely related to serum levels and can occur at therapeutic doses; serum lithium determinations are required to monitor therapy." Review of the plan of care, dated on 7/24/12, revealed the resident receives the following medications on either a routine or prn (as needed) basis: lisinopril, lithium carbonate,	F 428		

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remeron, risperdal, seroquel XR (extended release), wellbutrin XL (extended release), and tylenol. However the care plan lacked the specific information related to the monitoring of the adverse associated with the administration with these medications with black box warning.

Review of the medication administration record (MAR), dated July 2012, failed to identify these medications with black box warnings and failed to reveal the specific black box warning and monitoring of adverse consequences associated with the administration of the medications.

On 7/31/12 at 3:30 PM, the resident ambulating in the hall, and the gait is steady.

On 7/31/12 at 4:00 PM, licensed nursing staff H reported, "Black box warnings are really bad side effects of the medication. The side effects are listed on the MAR."

On 7/31/12 at 4:00 PM, direct care staff I reported, " Black box warnings are listed on the MAR and on the care plan. I have to look them up on the care plan."

On 7/31/12 at 4:15 PM, licensed administrative staff A reported," I just received a new corporate policy to change the care plans with BBW (black box warning). We are adding the specific BBW to the care plans as they come due. Prior to this we just had a laminated sheet that identified the BBW for each medication, but not specific to the resident. However the facility failed to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings."

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F 428	Continued From page 47 On 8/1/12 8:25 AM, licensed administrative nursing staff E reported, " We originally identified the medications on the plan of care and identify they have a BBW, but not putting the specific warning on the care plan." On 8/1/12 9:45 AM, licensed nursing consultant staff G reported, " The corporation has not implemented any changes yet and the plan is on hold. Furthermore, staff confirmed the facility needs to have a system to monitor side effects for black box warnings." On 8/1/12 at 4:00 PM, licensed administrative staff A reported, " I do not have a policy for black box warnings." On 8/1/12 at 4:15 PM, pharmacy consultant F reported, " I have recommended several times to the facility to add the specific black box warning to the medications on the plan of care... I was not aware the facility was making the resident's care plans non-specific regarding BBW." The facility failed to follow the consultant pharmacist recommendations to identify medications with applicable Black Box Warnings, to ensure staff monitored for potential adverse consequences associated with the administration of Lithium Carbonate. - The clinical record of resident #91, revealed the resident admitted to the facility on 2/20/12, with the following diagnoses which included; schizoaffective disorder (a mental disorder characterized by recurring distortions in perception and disordered thinking), and	F 428		

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hypertension (high blood pressure).

The physician orders revealed the following medications with Black Box Warning :

Clozaril 200 mg (milligrams) two times daily, ordered 2/20/12, for diagnoses of schizoaffective disorder.

The 2011 Lexi-Comp's Geriatric Dosage Handbook,16th Edition, page 380-381, identified Clozapine (Clozaril) with the following black box warning: "Significant risk of agranulocytosis, potentially life-threatening. Seizures have been associated with clozapine use in a dose-dependent manner. Fatalities due to myocarditis have been reported; highest risk in the first month of therapy, however, later cases also reported. May cause orthostatic hypotension (with or without syncope)."

Triamterene/ hydrochlorathiazied 37.5 mg/25 mg, in the morning, ordered on 2/20/12, for diagnoses of hypertension.

The 2011 Lexi-Comp's,16th Edition,Geriatric Dosage Handbook, page 1806, identified Triamterene with the following black box warning:" Hyperkalemia can occur; patients at risk include those with renal impairment, diabetes, the elderly, and the severely ill. Serum potassium levels must be monitored at frequent intervals especially when dosages are changed or with any illness that may cause renal dysfunction."

Depakote 750 mg, in the morning, and 1000 mg at bedtime, ordered on 2/20/12, for diagnoses of

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F 428	Continued From page 49 schizoaffective disorder. The 2011 Lexi-Comp's Drug Reference Geriatric Dosage Handbook,16th Edition, page 509 identified Depakote with the following black box warning: "Hepatic failure resulting in fatalities has occurred in patients. Cases of life-threatening pancreatitis, occurring at the start of therapy or following years of use, have been reported." Naproxen 375 mg, twice daily with food for three weeks, ordered on 7/11/12, with a stop date of 7/31/12, for diagnosis pain. The 2011,16th Edition, Lexi-Comp's Geriatric Dosage Handbook page 1213, identified Naproxen: with the following black box warning:" NSAIDs (nonsteroidal anti-inflamatory drug) may increase risk of gastrointestinal irritation, inflammation, ulceration, bleeding, and perforation. NSAIDs are associated with an increased risk of adverse cardiovascular thrombotic events, including and myocardial infarction and a stroke." Review of the plan of care, dated 5/29/12, revealed the resident received the following medications on either a routine or PRN (as needed) basis: clozaril, depakote, prolixin, triamterene/hydrochlorathiazide, and tylenol. However the care plan lacked the specific information related to the monitoring of the adverse associated with the administration with these medications with black box warning. Review of the medication administration record (MAR), dated July 2012, revealed the following medications with a black box warning;	F 428		

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triamterene/hydrochlorithiazide, prolixin, naproxen, clozaril, depakote and tylenol. However the facility failed in monitoring of the adverse consequences associated with their administration.

Observation on, 8/1/12 at 11:45 AM, the resident ambulating in the hall, by self. The gait is steady, the resident without any Parkinson type symptoms.

On 7/31/12 at 4:00 PM, licensed nursing staff H reported, "Black box warnings are really bad side effects of the medication. The side effects are" listed on the MAR.

On 7/31/12 at 4:00 PM, direct care staff I reported, " Black box warnings are listed on the MAR and on the care plan. I have to look them up on the care plan."

On 7/31/12 at 4:15 PM, licensed administrative staff A reported," I just received a new corporate policy to change the care plans with BBW (black box warning). We are adding the specific BBW to the care plans as they come due. Prior to this we just had a laminated sheet that identified the BBW for each medication, but not specific to the resident. However the facility failed to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings."

On 8/1/12 8:25 AM, licensed administrative nursing staff E reported, " We originally identified the medications on the plan of care and identify they have a BBW, but not putting the specific warning on the care plan."

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F 428	Continued From page 51 On 8/1/12 9:45 AM, licensed nursing consultant staff G reported, " The corporation has not implemented any changes yet and the plan is on hold. Furthermore, staff confirmed the facility needs to have a system to monitor side effects for black box warnings." On 8/1/12 at 4:00 PM, licensed administrative staff A reported, " I do not have a policy for black box warnings." On 8/1/12 at 4:15 PM, licensed pharmacy consultant F reported, " I have recommended several times to the facility to add the specific black box warning to the medications on the plan of care. ..I was not aware the facility was making the resident's care plans non-specific regarding BBW" The facility failed to follow the consultant pharmacist recommendations to identify medications with applicable Black Box Warnings, to ensure staff monitored for potential adverse consequences associated with the administration of Clozaril, Triamterene, Depakote and Naproxen for this resident. - A review of resident # 17's face sheet, medical record revealed an admission date of 8/29/96, with diagnoses which included: schizophrenic disorders (a long term mental illness in which a person loses touch with reality). Physician's orders revealed the following medications with black box warnings: Depakene suspension, 250 mg (milligrams) per 5 ml (milliliters), give 30 ml, by mouth, at every	F 428		

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bedtime, ordered on 10/20/07, for the diagnosis of schizophrenic disorders.

The 2011 Geriatric Dosage Handbook, 16th edition, page 1836, identified the following black box warning for Depakene: [U.S. Boxed Warning]: " Hepatic failure resulting in fatalities has occurred in patients. Cases of life-threatening pancreatitis, occurring at the start of therapy or following years of use, have been reported in adults and children. "
Fazaclo (Clozapine), by mouth, 300 mg at 4:00 pm, and 600 mg with every bedtime, ordered on 6/10/06, for the diagnosis of schizophrenic disorders.

The 2011 Geriatric Dosage Handbook, 16th edition, page 380 - 381, identified the following black box warning for Clozapine: [U.S. Boxed Warning]: " Significant risk of agranulocytosis, potentially life- threatening. Seizures have been associated with clozapine use in a dose-dependent manner. Fatalities due to myocarditis have been reported; highest risk in the first month of therapy, however, later cases also reported. May cause orthostatic hypotension (with or without syncope). "

Review of the plan of care, revised on 7/3/12, directed staff of "[The resident] receives the following medication on either a routine of PRN [as needed] basis: Depakene, Fazaclo, Risperdal, and Tylenol. These medications have a black box warning. Please be alert to the potential adverse effects/ side effects listed on [his/her] MAR [medication administration record]."
However, the care plan lacked the specific information related to the monitoring of the

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adverse conquences associated with administration of these medications with black box warnings.

Review of the medication administration record, dated July 2012, failed to identify these medications with black box warnings and failed to reveal the specific black box warning and monitoring of adverse consequences associated with the administration of the medications.

On 7/31/12 at 2:19 pm, observation revealed the resident ambulated in a television room and paced in circles.

On 7/31/12 at 4:00 pm, licensed nursing staff H reported, "Black box warnings are really bad side effects of the medication. The side effects are listed on the MAR."

On 7/31/12 at 4:00 pm, direct care staff I reported, "Black box warnings are listed on the MAR and on the care plan. I have to look them up on the care plan."

On 7/31/12 at 4:15 pm, licensed administrative staff A reported,"I just received a new corporate policy to change the care plans with BBW (black box warning). We are adding the specific BBW to the care plans as they come due. Prior to this we just had a laminated sheet that identified the BBW for each medication, but not specific to the resident. However, the facility failed to address the monitoring of the resident for adverse consequences associated with the administration of these medications with black box warnings."

On 8/1/12 8:25 am, licensed administrative

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nursing staff E reported, "We originally identified the medications on the plan of care and identify they have a BBW, but not putting the specific warning on the care plan."

On 8/1/12 at 9:45 am, licensed nursing consultant staff G reported, "The corporation has not implemented any changes yet and the plan is on hold. Furthermore, staff confirmed the facility needs to have a system to monitor side effects for black box warnings."

On 8/1/12 at 4:00 pm, licensed administrative staff A reported, "I do not have a policy for black box warnings."

On 8/1/12 at 4:15 pm, pharmacy consultant F reported, "I have recommended several times to the facility to add the specific black box warning to the medications on the plan of care. ...I was not aware the facility was making the resident's care plans non-specific regarding BBW."

The facility failed to follow the consultant pharmacist recommendations to identify medications with applicable black box warnings, to ensure staff monitored potential adverse consequences associated with the administration of Depakene, Fazaclo, Risperdal, and Tylenol for this resident.